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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/815,336      | 03/23/2001  | Anthony Nicolas Kalloo | 2784-25             | 4418             |

23117 7590 04/16/2007  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

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| EXAMINER |
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SHAY, DAVID M

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| ART UNIT | PAPER NUMBER |
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3735

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/16/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

09/815,336

Applicant(s)

KALLOO ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-19, 21, 22 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-19, 21, 22, and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 12, 2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in combination with McNeely et al. Wilk teaches a method such as claimed except the specific mention of dilating the opening after it is made; the use of balloons; use of electrical energy in combination with the needle; and using a clip to seal the incision (please note that the absence of the use of a clip implies the absence of other steps predicated thereon, such as the disposing of a clip applicator). McNeely et al teach a method of dilating a stomach wall including inserting a needle to form an incision, advancing a guide wire through the incision; advancing a dilation balloon over the guide wire; dilating the incision with the dilation balloon, and advancing a tubular member into the dilated incision. It would have been obvious to the artisan of ordinary skill to employ the dilation steps of McNeely et al in the method of Wilk, since the method of Wilk requires the incision be made by a device in an auxiliary channel of the endoscope, which will necessarily be of considerably smaller gauge than the endoscope, thereby requiring dilation of the smaller opening made by the smaller device, and to first withdraw the balloon dilator before advancing the endoscope, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result;

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and to situate the balloon on the needle knife conduit, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and since this would reduce the number of steps required to perform the operation, thereby saving time; and in any case to employ a clip to close the incision and the recited steps, since these are well known in the art and commercially available (see the paragraph spanning pages 15 and 16 of the instant disclosure), thus producing a method such as claimed.

Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in combination with McNeely et al as applied to claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, and 36 above, and further in view of Laufer. Laufer teaches a method of accessing an internal organ including the use of a cauterizing incision instrument and the use of balloons to seal the conduit to either side of the incision in the organ wall. It would have been obvious to the artisan of ordinary skill to employ a cauterizing incision device, as taught by Laufer in the combined method of Wilk and McNeely et al, since this is equivalent to the unheated needle of Wilk as shown by Laufer, and/or the balloon sealing means of Laufer in the combined method of Wilk and McNeely et al, since the use of balloons is not critical and provides no unexpected result, thus producing a method such as claimed.

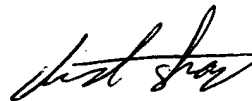
Applicant's arguments with respect to claims 1-19, 21, 22, and 36 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam, can be reached on Monday, Tuesday, Wednesday, and Thursday at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330